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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/991,544	11/16/2001	Jon Vein	269/202	3052

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PERKINS COIE LLP
POST OFFICE BOX 1208
SEATTLE, WA 98111-1208

EXAMINER	
NAFF, DAVID M	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 11/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/991,544	VEIN, JON	
	Examiner	Art Unit	
	David M. Naff	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 November 2001*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disp sition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) *20-23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Claims in the application are 1-23.

RESTRICTION

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-19, drawn to a non-human meat product containing non-human muscle cells grown *ex vivo*, and method of making non-human meat products by culturing non-human muscle stem cells *ex vivo*, seeding the cells on a support and growing the cells, classified in class 435, subclass 325.

II. Claim 20, drawn to a method of producing non-human meat by co-culturing non-human muscle cells and non-human fat cells *ex vivo*, seeding the cells on a support and growing the cells, classified in class 435, subclass 373.

III. Claim 21, drawn to a method of producing non-human meat by culturing non-human muscle stem cells *ex vivo*, seeding the cells on a support, treating the cells with fatty acids to trans-differentiate the cells into adipocytes, and growing the adipocytes, classified in class 435, subclass 377.

IV. Claims 22 and 23, drawn to a method of producing non-human meat products by culturing non-human cartilage cells *ex vivo*, seeding the cells on a support, culturing non-human muscle cells with the non-human cartilage cells on or around the support, and growing the non-human muscle cells, classified in class 435, subclass 395.

The inventions are distinct, each from the other because:

Inventions I is related to inventions II, III and IV as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product can be made by a different process. The product of I can be made without co-culturing and growing different cells together on a support as in II, without treating with fatty acids as in III, and without culturing muscle cells with cartilage cells after cartilage cells are cultured and seeded on a support as in IV.

The methods of producing non-human meat as required by claims 14-19 of I, and by the claims of II, III and IV, each require different method steps such that each method can be performed without carrying out any other method.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

During a telephone conversation with Michael J. Wise on 11/19/03 a provisional election was made with traverse to prosecute the invention of I, claims 1-19. Affirmation of this election must be made by applicant in replying to this Office action. Claims 20-23 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Claim Objections

Claims 12, 13, 15 and 17-19 are objected to because of the following informalities: claims 12 and 13 depend on claim 10 which does not require cartilage cells. It appears the claims should depend on claim 11. Claims 15 and 17-19 depend on the method of claim 13 which does not require a method. These claims should be dependent on claim 14. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-7 and 14-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bowlin et al (6,592,623 B1) in view of Vacanti et al (6,348,069 B1).

The claims are drawn to a non-human meat product comprising non-human muscle cells grown *ex vivo*. Also claimed is a method of producing non-human meat products by culturing non-human stem cells *ex vivo*, seeding the cells onto a support and growing the cells to produce the meat product.

Bowlin et al disclose producing engineered muscle for use as an implant to replace dysfunctional muscle tissue by culturing cells that form muscle tissue in the presence of a matrix to produce muscle tissue (col 3, lines 5-10 and col 10, lines 1-28). The cells used may be stem cells or muscle cells (col 7, line 21 and col 11, line 27).

Vacanti et al discloses producing engineered tissues by expanding bovine, ovine or lamb muscle cells in culture, seeding the cells on a scaffold and growing the cells to confluence (col 8, lines 32-61).

When desiring to replace dysfunctional muscle tissue in an animal such as a bovine, ovine or lamb, it would have been obvious to produce

the engineered muscle of Bowlin et al for such replacement, and it would have been obvious use as the cells to form the muscle, cells from a bovine, ovine or lamb as suggested by Vacanti et al using muscle cells from these animals to engineered tissue by culturing muscle cells, seeding the cells on a scaffold and growing the cells to confluence.

The resultant engineered muscle tissue for the animal will be non-human and produced by culturing muscle cells *ex vivo*, and will inherently be meat that can be consumed. The fact that the muscle tissue produced by Bowlin et al is intended as an implant does not make it non-consumable. The procedure of Bowlin et al will result in engineered muscle substantially free of microbial contamination as required by claims 5 and 19. Bowlin et al disclose using electrical pacing (col 12, lines 40-41) that would suggest using an electrical current as in claims 7 and 16. Stem cells as in claim 14 are also disclosed by Bowlin et al as noted above. Pluri-potent and toti-potent cells as in claim 6 are well known cells, and their use would have been obvious. Moreover, it appears stem cells of Bowlin et al are inherently such cells. Incorporating nutrients as in claim 17 would have been obvious to supply nutrients for cell growth.

Claim Rejections - 35 USC § 103

Claims 8-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 1-7 and 14-19 above, and further in view of Skaar et al (5,746,649) and Naughton et al (5,863,531).

Claim 8 requires the meat product to further comprise non-human adipocyte cells grown *ex vivo*, and claim 11 requires the meat product to further comprise non-human cartilage cell grown *ex vivo*.

Skaar et al disclose (col 1, lines 17-37) that meat contains fat cells and connective tissue dispersed throughout muscle tissue.

Naughton et al disclose growing stromal cells with cells of another type on a support (col 4, lines 25-30), and after forming stromal tissue on the support, inoculating the support with tissue specific cells (paragraph bridging cols 13 and 14).

When using animal cells to form the muscle engineered muscle tissue of Bowlin et al as set forth above, it would have been obvious to include adipocyte cells (fat cells) and cartilage cells with the muscle forming cells since fat cells and cartilage are normal components of muscle tissue as disclosed by Skaar et al, and including these cells would have been expected to make the muscle tissue of Bowlin et al more similar to natural muscle tissue. It would have been apparent from Naughton et al that different cell types can be cultured together. Having the cartilage cells between a support and muscle cells as in claim 12 would have been obvious from Naughton et al culturing stromal cells which may include connective tissue cells such as chondrocytes (col 4, line 30) on a support and then culturing tissue specific cells on the support. Trans-differentiating as in claim 9 would have been obvious from Bowlin et al using stem cells that differentiate into another cell type. Bowlin et al disclose using mechanical stretching (col 12, lines 20-39) which would have

suggested mechanical stress as in claim 13. As noted above, Bowlin et al disclose electrical pacing, and this would have suggested electric or oscillating current as in claim 16.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is 703-308-0520. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 703-308-4743. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

David M. Naff
Primary Examiner
Art Unit 1651

DMN
11/21/03